

Remarks

Status of Claims

Claims 1-13 and 16-22 are rejected. Claim 17 and 18 are amended. Claim 23 is added. Claims 1-9, 11-13, and 16-23 are pending.

New claim 23 and the claim amendments are supported by the specification as filed. No new matter is added. For instance, but without limitation, with respect to new claim 23, page 4 of the specification describes support for the needle having a needle slot (e.g. slot 104d).

§103 Rejections

The rejection of the claims as obvious over Burbank (5,526,822) in view of Banik (6053877) and further in view of Bryan (6488636) is improper for all the reasons set forth in the prior responses.

In particular, and without limitation, the Examiner is requested to reconsider and allow the claims in view of the following:

Claim 1.

First, there is no motivation to combine the references as suggested by the Examiner.

Claim 1 recites, among other things, the cutter has a plurality of holes spaced from the distal end of the cutter.

The Examiner refers to Bryan as showing an analogous device with a basket tube 18 having a plurality of holes 114. Actually, Bryan teaches a Basket portion 19 has a smaller diameter than basket tube 18, and that it is basket portion 19 that has holes 114 in order to be able to communicate with suction provided through a thrust tube 16. (see column 6, lines 16-35)

Moreover, Bryan goes on to explain at column 7, lines 56-column 8, lines 35, that during operation, cutting tube 24 is fully advanced distally to enclose basket portion 19. Clearly, the portion of Bryan that has holes 114 is not the cutter tube of Bryan, but is a separate component from the cutter tube.

It is respectfully urged that Examiner has not provide any motivation in the prior art to provide a cutter as recited in Claim 1. It is respectfully urged that Bryan does not teach or suggest that the cutting tube 24 has a plurality of holes spaced from a distal end of a cutter, or a plurality of holes formed transversely through the sidewall of a cutter, or such holes positioned for providing vacuum axially through a cutter when samples are disposed within a sample tube within the cutter.

So, even if one used the teachings of Bryan to modify Burbank, there is still no motivation add holes 114 to the cutter of Burbank where Bryan's holes 114 are on a component different from the cutter tube of Bryan.

Second, even if one combined the references, the resulting combination would not provide the subject matter of Claim 1.

Claim 1 recites, among other things, that the sample tube comprises a vacuum lumen and a sample lumen, and wherein the vacuum lumen extends along side of at least a portion of the sample lumen.

The Examiner appears to admit that Burbank in combination with Banik and Bryan does not teach a sample tube comprising a vacuum lumen and a sample lumen.

The Examiner does not have a prima facie case of obviousness where the combined references fail to disclose all the claim limitations, as acknowledged by the Examiner, and the rejection should be withdrawn.

The Examiner attempts to state that because Burbank discloses the biopsy needle that comprises a vacuum lumen 652, one would be motivated to add a vacuum lumen to a sample tube. The Examiner has provided no motivation in the art of record to support this modification of the references, references which even when combined, don't teach all the elements set forth in claim 1.

Third, if one tried to add a vacuum lumen of Burbank to a sample tube, as the Examiner suggests, it is respectfully urged the result would be inoperable. Claim 1 recites, among other things, that the sample tube is advanceable in the cutter. It is respectfully urged that adding the

vacuum lumen 652 of Burbank to another structure, the resulting structure would not be advanceable within a cutter as recited in Claim 1. If the Examiner agrees, the Examiner is respectfully requested to point out specifically how one could add the lumen 652 of Burbank to another structure and still have the structure be advanceable in the cutter of Burbank. It is respectfully urged that would simply not be possible.

Claim 16:

The Examiner is requested to reconsider the rejection of Claim 16 in view of the comments above and those made previously.

In addition, Claim 16 recites, among other things a hollow biopsy needle having a closed distal end and a lateral tissue receiving port spaced proximally of the closed distal end;

In contrast, Banik teaches jaws 14 at the distal end of the Banik device. It is respectfully urged that the “sample tube” the Examiner refers to in Banik works in a different manner than the device of Burbank. It is respectfully urged that there would be no motivation to combine the two as the Examiner suggests, and that such a combination would be inoperative. If the Examiner disagrees, the Examiner is respectfully requested to explain specifically how the two references would be combined to provide a workable device, or withdraw the rejection.

Claim 17.

The rejection of Claim 17 is improper for at least the following reasons.

First, Claim 17 recites, among other things, advancing a hollow cutter in a needle. The Examiner states that Banik discloses a hollow sample tube 20 advanced in a “hollow cutter 14.” This is not correct. Banik actually teaches that element 14 is one of two jaws 14,14’, not a hollow cutter. Accordingly, the Examiner cannot fairly characterize Banik as teaching or suggesting a hollow cutter, or advancing a sample tube in a hollow cutter.

Second, Claim 17 is amended to recite drawing tissue into a side tissue receiving port of a hollow needle. It is respectfully urged this is contrary to the very teachings of Banik and Banik’s jaw

assembly. One would not be motivated to look to Banik's device employing jaws at the distal end of a device to modify Burbank as the Examiner suggests.

Third, even if one combined Banik and Burbank, and even if (for the sake of argument only), one considered the jaws 14,14' of Banik to be a hollow cutter, the rejection would still be improper. That is because combining the two references would not teach:

wherein at least a portion of the act of advancing the hollow sample tube is performed after the cutter has reached the distalmost position and after the cutter has encapsulated the severed tissue sample

Note that in Banik, even if the jaws 14,14' are considered a hollow cutter, this step is not taught or suggested. Instead, as the Examiner notes, Banik teaches at col. 6, lines 43-48 that:

As the *jaws close in radial motion*, they urge tissue separated from the surface slightly proximally. *At the same time*, the sample tube 20 moves axially distally. The combined effects of the jaws and the tube tend to urge or stuff sample into the open end 21 of the sample tube 20. (italics added)

Accordingly, it is clear that the act of advancing the sample tube 20 of Banik is not performed after the jaws 14,14' of Banik have reached a distal most position. In addition, Banik teaches that the jaws close in radial motion, not by axial motion. Accordingly, the combination of Burbank and Banik would not teach all the method steps of Claim 17.

It is respectfully urged that the Examiner must provide some basis in the prior art for not only combining the references, but also for modifying the proposed combination.

Here, the Examiner has combined the references with no motivation, and then "filled in the blanks" by assuming that one would have some motivation to further modify the combined references to provide a feature that is not disclosed in any of the references.

Regarding New claim 23, it is respectfully urged that even if one combined the references as suggested by the Examiner, the resulting combination would not teach the subject matter of

Claim 23, including but not limited to a needle having an axially extending slot positioned proximal of a side tissue receiving port, or such an axially extending slot communicating between the cutter lumen and the vacuum lumen.

Conclusion

While several distinctions have been noted over the art of record, Applicant notes that there are several other limitations recited in the present claims that are neither taught nor suggested by the art of record. Applicant expressly reserves all rights and arguments, including those made in previous responses, with respect to distinctions not explicitly noted herein. In addition, to the extent that the amendments constitute a narrowing of the claims, such narrowing of the claims should not be construed as an admission as to the merits of the prior rejections. Indeed, Applicant traverses the rejections and preserves all rights and arguments. To the extent that any particular statement or argument by the Office in the pending Office Action has not been explicitly addressed herein, the same should not be construed as an acquiescence or admission by the Applicant that such statements or arguments by the Office are accurate or proper.

Based on the foregoing, all pending claims are in a condition for allowance. Accordingly, Applicant respectfully requests reconsideration and an early notice of allowance.

Respectfully submitted,

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